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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,893	10/14/2003	J. Milton Harris	044646/262893	4856

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EXAMINER	
FISHER, ABIGAIL L	
ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/684,893	HARRIS, J. MILTON	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-27* is/are pending in the application.

4a) Of the above claim(s) *25-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-9, 17-18 and 23-24* is/are rejected.

7)☒ Claim(s) *10-13,15,16 and 19-22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Receipt of Amendments/Remarks filed on May 18 2008 is acknowledged. Claims 14 were/stand cancelled. Claims 1-13 and 15-27 are pending. Claims 25-27 are withdrawn as being directed to a non-elected invention. Claims 1-13 and 15-24 are directed to the elected invention. The examiner would like to note that the search has been expanded to include all species of the hydrolysable linkages. Therefore, previously withdrawn claims 15-17 are examined on the merits herein as well.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claims 10-13, 15-16 and 19-22 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 17-18 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jamiolkowski et al. (US Patent No. 5698213).

Applicant Claims

Applicant claims a hydrogel crosslinked polymeric structure comprising poly(ethylene glycol) (PEG) polymers in the absence of non-PEG polymers. The PEG polymers have at least some hydrolytically unstable linkages between said PEG polymers that are hydrolysable under hydrolysis conditions, said hydrolysable linkages comprising linkages selected from the group consisting of carboxylate esters, phosphate esters, imines, hydrazones, acetals, orthoesters, and oligonucleotides.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Jamiolkowski et al. is directed to hydrogels of absorbable polyoxaesters. The polymer are utilized to produce hydrogels and medical devices (abstract). The exemplified poly"oxa"esters are made from polyglycol diacid (example 4) and ethylene

glycol. This acid comprises polyethylene gycol repeating units. The resulting ester comprises an internal carboxylate. It is taught that one of the beneficial properties of the polymers is that the ester linkages are hydrolytically unstable and therefore the polymer readily breaks down into small segments when exposed to moist bodily tissue (column 5, lines 46-50). It is taught that the polymers can be crosslinked to affected mechanical properties. The crosslinking may be chemical or physical (column 9, lines 28-30). The polymer hydrogel can be utilized as wound dressings (column 11, lines 13-14). Claimed products include a drug delivery matrix comprising the polymer and a drug (claim 8).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Jamiolkowski et al. do not exemplify the polymer of example 4 crosslinked or in a hydrogel comprising a drug. However, Jamiolkowski et al. do indicate the polymers can be crosslinked, in the form of a hydrogel, and in a drug delivery matrix.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to crosslink the polymer of example 4 of Jamiolkowski et al. One of ordinary skill in the art would have been motivated to crosslink the polymer as Jamiolkowski et al. teach that the polymers of the invention can be crosslinked and crosslinking can be utilized to affect the mechanical properties of the polymer.

It would have been obvious to one of ordinary skill in the art to combine the exemplified polymer of Jamiolkowski et al. with a drug and form a drug delivery matrix

hydrogel. One of ordinary skill in the art would have been motivated to form this drug delivery matrix as Jamiolkowski et al. teach that this is one use of the polymers of the invention. One of ordinary skill in the art would have been motivated to formulate this type of drug delivery matrix as Jamiolkowski et al. teach that the polymers of the invention due to their hydrolytically unstable linkages readily break down into small segments when exposed to moist bodily tissue.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 15-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6258351. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a hydrogel crosslinked polymeric structure comprising poly(ethylene glycol) (PEG) polymers in the absence of non-PEG polymers. The PEG polymers have at least some hydrolytically unstable linkages between said PEG polymers that are hydrolysable under hydrolysis conditions, said hydrolysable linkages comprising linkages selected from the group consisting of carboxylate esters, phosphate esters, imines, hydrazones, acetals, orthoesters, and oligonucleotides.

Patent '351 claims a degradable crosslinked polymeric structure comprising hydrolytically unstable linkages between one or more hydrolytically unstable linkages between one or more chemically crosslinked non-peptidic polymers. One polymer claimed is poly(ethylene glycol). The hydrolysable linkages claimed are the same as those of the instant invention. It is claimed that the hydrolytically unstable linkages degrade to release conjugates of bioactive agents. A specific structure also claimed comprises hydrolytically stable linkages as well. Specific claimed structures comprise only polyethylene glycol poymers.

Patent '351 does not claim the polymeric structure is a hydrogel. However, Patent '351 indicates in the title and abstract that the polymers are hydrogel forming

polymers. Therefore, the scopes of the claims of Patent '351 and the instant application overlap and thus they are obvious variants of one another.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF
/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616